Roche

Committee Secretary
Senate Legal and Constitutional Committees
PO Box 6100
Parliament House
Canberra ACT 2600

25 February 2011

Submission to the inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*

Dear Sir/Madam

Please find enclosed a submission from Roche (Roche Products Pty Limited and Roche Diagnostics Australia Pty Limited) in relation to the Senate Committee inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill 2010.*

Thank you for the opportunity to provide comment on this proposed legislation and we would welcome the opportunity to address the committee if public hearings are scheduled.

It would be appreciated if you could add us to any mailing list around the progress of this inquiry.

If you require any further information please do not hesitate to contact

Sincerely,

Roche Products Pty Limited

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Corporate Affairs Manager

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Roche

Submission to the Senate Standing Committee on Legal and Consitutional Affairs in relation to the:

Patent Amendment (Human Genes and Biological Materials) Bill 2010

Committee Secretary
Senate Legal and Constitutional Committees
Parliament House, Canberra

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Roche Products Pty Limited
Roche Diagnostics Australia Pty Limited

Background

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics.

Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammatory and autoimmune diseases, metabolism and central nervous system.

Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management.

Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.

In 2010, Roche invested over $9 billion (AUD) in research and development worldwide, including approximately $36 million (AUD) in pharmaceuticals in Australia. Genentech, United States, is a wholly owned member of the Roche Group.

Roche has a majority stake in Chugai Pharmaceutical, Japan.

For more information: www.roche-australia.com.

For any further information in relation to this submission please contact:

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Executive summary

Roche Products Pty Limited and Roche Diagnostics Australia Pty Limited (Roche) opposes the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (the Bill) on the following grounds:

1. No review into intellectual property or gene patents has ever recommended the introduction of legislation of this sort.

2. It could lead to detrimental outcomes for patients in Australia.

3. Medical research and development in Australia would be impacted.

4. The proposal would make Australia an outlier in relation to intellectual property law globally.

Case study: *Breast Cancer - Herceptin (trastuzumab) and HER2 testing*

Herceptin (trastuzumab) belongs to a group of medicines known as anti-neoplastic (or anti-cancer) agents. There are many different classes of anti-neoplastic agents. Herceptin belongs to a class called monoclonal antibodies. Monoclonal antibodies are proteins made in a laboratory. These proteins are designed to recognise and bind to other unique proteins in the body.

Herceptin binds selectively to a protein called human epidermal growth factor receptor 2 (HER2). HER2 is found in large amounts on the surface of some cancer cells.

When Herceptin binds to HER2 it stops the growth and spread of the cancer cells.

Herceptin is approved in Australia for the treatment HER2 positive localised (early stage) and metastatic (late stage) breast cancer in combination with chemotherapy, and gastric cancer.[1]

Herceptin has been used by over 800,000 patients[2] worldwide.

Herceptin development and investment timeline

The development of Herceptin began in the early 1980s following the discovery that disturbances in one or more members of a family of genes can lead to the transformation of a normal cell into a cancer cell.

It is estimated that the cost of developing a drug is over USD$1.2 billion [3] (AUD$1.1 billion). Below is a timeline including the investment phases for the development of Herceptin.

It took around 17 years for this cancer drug to be developed before it was first approved by the Federal Drug Administration (FDA). For a company like Roche to invest over 1 billion dollars to develop a drug, we require certainty in relation to intellectual property law. This is not only important in one country but what is required is a globally consistent approach.

Date	Event	Investment Phase
1981	Genentech (A Member of the Roche Group) scientists first cloned and sequenced a portion of the human HER2 gene for the first time.	Lead Discovery Research 9 years
1985	Genenetch scientists were able to clone the first full-length human HER2 gene.	
1987	Genentech was able to develop the parent of Herceptin, mouse 4D5. It was at this time that	

[1] Herceptin (trastuzumab) Product Information, available at www.roche-australia.com
[2] PSUR Nov 2009.
[3] CP Adams and VV Brantner, *Spending on new drug development*, Health Econ 19: 130-141 (2010)

	the link between HER2 over-expression and a more aggressive type of breast cancer was also made.	
1990	Herceptin was first created in 1990 by humanizing the 4D5 mouse antibody directed at HER2.	
1992	First clinical trial (Phase I) for Herceptin commences.	Drug Development 6 years
1993	Phase II clinical trials commence.	
1995	Phase III pivotal trials for Herceptin with patients with HER2 over-expressing metastatic (late stage) breast cancer commence.	
August 1997	Australia patent for Herceptin granted (patent No. 675916)	
September 1998	Federal Drug Administration (FDA) approves Herceptin for metastatic (late stage) breast cancer	Available to Patients
	Therapeutic Goods Administration (TGA) approves Herceptin for late stage breast cancer	
October 2001	Australian Government funds Herceptin for the treatment of metastatic (late stage) breast cancer under a special Herceptin Program through Medicare Australia	
	TGA approves Herceptin for early stage breast cancer	
October 2006	Herceptin listed on the PBS for early stage breast cancer	

Introduction

Roche Products Pty Limited and Roche Diagnostics Australia Pty Limited are the Australian affiliates of F Hoffman La-Roche Limited (Roche). Roche would welcome the opportunity to address the the Senate Standing Committee on Legal and Consitutional Affairs (the Committee) in relation to this Bill if public hearing are held or be involved in any reviews around the issue of gene patents in the future.

We have had the opportunity to review the submissions of Medicines Australia and IVD Australia and would endorse the position put forward by these industry groups for opposing the Bill.

Currently in Australia it is not possible to patent human beings and the biological processes for their generation.[4]

We note that the purported purpose of the Bill is to "... *advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature.*

These biological materials even if they have been isolated, purified or synthetically made have not been transformed from products of nature into products of humankind."[5]

Unfortunately the proposed Bill would created an unpredicted and extremely wide exclusion to patentable material, while not advancing its purposed purpose. A plain reading of the Bill and its definition of "biological materials" and the ban on their "... *components and derivates, whether isolated or purified and however made, which are identical or substantially identical to such materials as they exist in nature"* would see the exclusion of a number of medical products.

In particular the types biological materials and their products what would be excluded from being patentable include: genes, nucleic acids, proteins, vaccines, antibodes, mAbs, microbes (bacteria & viruses), antibiotics, enzymes, hormones, immunglobulins and other blood products, stem cells, anti-toxins, anti-venoms, skin and other tissues, allergenics, probiotics, recombinant therapeutics.

Roche believes that biologic medicines could fall within the excluded products. Biologics are much more complex than the chemically clearly defined small molecules that still make up the majority of medicines. Biologics can be proteins (especially antibodies), DNA or RNA and are derived from living material using biotechnological processes. A leading example of a biological medicine is Herceptin (trastuzumab). We have provided Herceptin as a case study so that the Committee can

[4] Section 18(2) *Patents Act 1990*
[5] Explanatory Memorandum, *Patent Amendment (Human Genes and Biological Materials) Bill 2010*

better understand the research and development, length of time and investment that it takes to bring such a therapy to market.

In addition Roche is concerned about the consequences of passing the Bill on access to innovative treatments, detection of diseased and normal states and R&D in both universities and commercial organisations in Australia.

Reviews into Australian's patent laws

Since 2004 there has been four reports which have looked at gene patenting as an issue. These include:

- Australian Law Reform Commission 2004 – *Gene Patenting and Human Health*
- Advisory Council on Intellectual Property (ACIP) 2005 – *Patents and Experimental Law*
- Senate Community Affairs Committee 2009 – *Inquiry into Gene Patents*
- ACIP 2010 – *Patentable Subject Matter*

None of these reports or inquiries proposed that Australia's patent law should be amended to exclude genetic or biological materials from being patentable subject matter.

In November 2010 the Senate Community Affairs Committee in its report on the *Inquiry into Gene* Patents stated that:

"... the Committee determined that it would not recommend at this stage the Patents Act 1990 be amended to include an express prohibition on human genes and genetic products."[6]

This conclusion was reached despite the Community knowing of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* and explicitly referring to it.

In addition, in the recently released report by the ACIP, *Patentable Subject Matter*, it states:

"We have concluded that no persuasive case has been made to introduce a specific exclusion to prevent the patenting of human genes and genetic products."[7]

The ACIP report was the result of an extensive consultation and review process which commenced in July 2008. This expert review must been given considerable weight when examining if an amendment of the type proposed by the Bill is appropriate.

No review to date into intellectual property or gene patents has ever recommended the introduction of legislation of this sort proposed by the Bill.

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[6] p114, *Gene Patents*, Senate Community Affairs Committee, November 2009. Full report available at http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents_43/report/index.htm

[7] p14, *Patentable Subject Matter*, Advisory Council on Intellectual Property, December 2010

Patient outcomes and R&D in Australia

As noted in the introduction, the Bill would provide an extremely wide definition of the types of biological material that could not be patented.

In five years from now there is a consensus that the Pharmaceutical Benefits Scheme (PBS) will be providing more biologics such as breast and gastric cancer treatment Herceptin (trastuzumab).

Biologics are much more complex than the chemically clearly defined small molecules that still make up the majority of medicines. Biologics can be proteins (especially antibodies), DNA or RNA and are derived from living material using biotechnological processes.

If the Bill was passed we are concerned that biologic medicines like Herceptin would not be patentable in Australia. The consequences of this would be:

I. Pharmaceutical and biotechnology companies like Roche would be extremely unlikely to undertake clinical trials in Australia if their medications in development could not be patented here. Annually over 18,000 Australians are on clinical trials[8] which provides them with access to innovative medicines while they are in development.

II. Any change to the patent law would mean that it is extremely unlikely that a medical breakthrough requiring the patenting of biologic material would be developed in Australia. This is because companies would be unlikely to invest in any early research and development being undertaken here if their investment could not be protected.

    Roche is committed to finding the world's best scientific ideas wherever they are and developing them into medicines or diagnostics. Accessing external innovation through partnering is a crucial part of our R&D strategy. Specific to Australia, a large proportion of biological research is undertaken by our universities. Following proof of concept the university then seeks collaboration with a commercial organisation such as Roche to take the next crucial step "from Bench to Bedside" It is noteworthy a significantly increasing number of Australian universities are now filing for such patents both in Australia and worldwide. Unfortunately if there was any uncertainty as to the intellectual property protection of a potential partnering investment in Australia, it is unlikely a university or Roche would proceed to bring inventions to the patient.

III. If there was the possibility of a significant medical development, it would quickly be transferred off-shore where it could be patent protected and developed. As a consequence Australia would lose much of its biotechnology industry and research capacity. Scientists and even research clinicians would need to move overseas to be involved significant research.

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[8] Pharmaceuticals Industry Council, *Benchmarking Survey of Clinical Research in Australia*, 2010.

IV. In making the decision to launch an innovative medicine in Australia, pharmaceutical and biotechnology companies would have to first clearly weigh up the intellectual property risks. This may mean Australians could be denied access to new biological medicines altogether.

In summary if the Bill was passed it:

- **Could lead to detrimental outcomes for patients in Australia.**
- **Research and development in Australia would be impacted.**

Consistency with other jurisdictions

No other country has proposed any legislation of the type contemplated by this Bill. In fact the European Union has passed a Biotechnology Directive which states that:

"...it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;"[9]

In addition as a member of the World Trade Organisation, Australia is required to operate under the Agreement on Trade-Related Aspects of Intellectual Property Rights. Banning patents on biological materials would violate Article 27 which requires countries to make patent protection available without discrimination as to the field of technology.

The Bill would make Australia an outlier in relation to intellectual property law globally.

[9] Directive 98/44/EC of The European Parliament and of the Council, 6 July 1998. Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML